DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-553/S-001, S-002, S-004, S-006

Purdue Pharma L.P.
One Stamford Forum
Stamford, CT 06901-8850

Attention: Beth Connelly
U.S. Regulatory Affairs

Dear Ms. Connelly:

We acknowledge the receipt of your January 29, 1997 (S-001), January 31, 1997 (S-002), November 13, 1997 (S-004), and May 1, 2000 (S-006) submissions containing final printed labeling in response to our letters approving your supplemental new drug applications for OxyContin (oxycodone Hcl controlled-release) Tablets, 10, 20, 40, 80, and 160 mg.

We note that the FPL for supplements S-002, and S-004 have been superceded by the FPL for supplement S-006. They will be retained in our files.

We have reviewed the labeling that you submitted in accordance with our June 21, 1996, and March 15, 2000, letters and we find it acceptable.

If you have any questions, call Lisa Basham, Regulatory Project Manager, at (301) 872-7420.

Sincerely,

{See appended electronic signature page}

Cathie Schumaker
Chief, Projecr Management Staff
Division of Anesthetic, Critical Care, and
Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research